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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,466	11/06/2003	Maria Dalko	231064US0	8539

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

NOTIFICATION DATE	DELIVERY MODE
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12/18/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/701,466	Applicant(s) DALKO ET AL.	
	Examiner Frank I. Choi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20070411</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 6 and 12 are objected to as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the agents listed in claim 14 or the treatment of wrinkles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The claims are directed to treatment of wrinkles or fine lines with at least one compound of formula (I).

The state of the prior art and the predictability or lack thereof in the art:

The prior art of record does not appear to disclose use of the claimed compounds to treat wrinkles or fine lines or the compounds listed in claim 14.

The amount of direction or guidance present and the presence or absence of working examples:

It appears that only one compound is tested for relaxation of diaphragm muscle. There is no example that shows that the compounds are effective in treating wrinkles and fine lines. Also

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there does not appear to be examples of the agents falling within the scope of the broad categories of claim 14.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim numerous compounds and no specified amount for treatment of fine lines and wrinkles. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to show that the compounds would be effective in treating fine lines and wrinkles and what compounds would fall within the scope of the broad categories of claim 14. Further, there is no evidence of any agent that would completely prevent degradation of dermal or epidermal macromolecules, as such, one of ordinary skill in the art would be required to do undue experimentation in order to determine what compounds prevented degradation of the same.

The Examiner had duly considered the Applicant's arguments but deems them unpersuasive.

The claims are directed to treatment methods or else why would they be applied to wrinkles. The Applicant has not shown that they are effective against wrinkles. The Applicant provides no evidence as to what compounds would fall within the scope of claim 14. The unsupported argument that one of ordinary skill in the art would know the compounds is not sufficient to overcome the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,4, 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how Y can be limited to a C5-C7 alkylethylene or di (C5-C7)

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alkylpropylene chain but in claim 4, Y can be unsubst., branched C11-C16 chain and in claim 5, Y can be di(C5-C7) dialkyl pentylene chain.

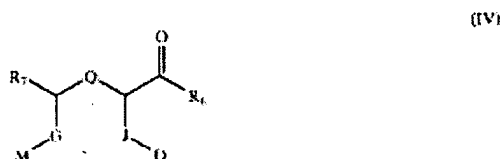
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5,7-11,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. 6,632,830 (Acton et al.)

Acton et al. discloses an ACE-2 inhibiting compound and compositions which have the following structure:



It is disclosed that M can be phenyl, G can be C1-C6 alkyl or alkenyl, R7 can be hydrogen, Q can be NH or NR₃ where R₃ can be substituted or unsubstituted C1-C5 straight or branched chain, R₆ can be hydroxyl or branched or unbranched lower alkyl or aryl group and J is an alkyl or alkenyl moiety and D is hydrogen or alkyl or alkenyl (Abstract, Column 12, lines 22-68, Column 3, lines 1-63). Examiner directs Applicant to the HCAPLUS abstract of WO 2000066104 as an example of a representative compound.

Instant claims differ from the reference in that they are of different generic scope. It had been held by Courts that the indiscriminate selection of "some" from among "many" is

considered *prima facie* obvious. In re Lemin, 141 USPQ 814 (1964); National Distillers and Chem. Corp. V. Brenner, 156 USPQ 163.

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare compounds embraced by the genus of the above cited references with the expectation of obtaining additional beneficial compounds. The instant claimed compounds would have been suggested to one skilled in the art.

One having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render *prima facie* obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. V. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
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12/10/07


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